

### **REMARKS**

Claims 1-7 and 9-14 are pending in the instant application and Claims 8, and 15-21 have been canceled. As outlined above, Claims 1-3, 7, and 9-14 have been amended. No new matter is introduced by the amendments to the claims. Support for the amendments to the claims can be found throughout the specification and drawings, particularly paragraphs [0091] - [0094] of the application.

### **Election/Restriction**

The Examiner has finalized the restriction requirement contained in the Office Action of October 4, 2006. In response, Applicants have canceled non-elected claims 15-21.

### **Drawings**

The Examiner has objected to the drawings as failing to comply with 37 C.F.R. 1.83. In particular, the Examiner asserts that Figures 1 and 2 have sequences that are included in the specification and the sequence listing. Applicants have reviewed the Figures in question and are unable to identify any amino acid or nucleic acid sequences. Accordingly, Applicants respectfully request the Examiner to withdraw this objection or more precisely identify the location of the sequences present in Figures 1 and 2.

### **Claim Objections**

Claim 1 is objected to by the Examiner. Applicants respectfully submit that Claim 1, as currently amended, conforms with the Examiner's suggested correction and thus withdrawal of this objection is respectfully requested.

## **Claims Rejections**

### **Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1-4 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner objects to the Applicant's use of the term "gene" in Claims 1-3 and 12-13. Claims 4-11 and 14 also stand rejected as depending from claims rejected on this ground.

Without acquiescing in the propriety of the Examiner's position, and solely to expedite prosecution of the instant application, Applicants have amended Claims 1-3 and 12-13 as suggested by the Examiner. In light of the foregoing, Applicants respectfully request withdrawal of this rejection.

Claims 10 and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in their recitations of "R-nj:Ac line," "W22/R-nj As line," "W22/R-nj Ag line," and "A188/R-nj::AC line." In particular, the Examiner asserts that the meanings of the cited recitations are not apparent to one of skill in the art.

Without acquiescing in the propriety of the Examiner's position, and solely to expedite prosecution of the instant application, Applicants have amended Claims 10 and 11 to recite "a line containing the active element Ac located in the R-nj chromosomal region such that excision of the said element Ac results in the production of anthocyan-containing sectors on the crown of the seed, including the embryo (R-nj::Ac allele)" and "line is selected from the group consisting of A188 and W22 lines made homozygous for said R-nj::Ac allele," respectively. Applicants

submit that in contrast to the Examiner's characterization, the various original alleles and lines described in Claims 10 and 11 are well known. For example, the R-nj allele is also named "Navajo" and has been known in the art for more than thirty years, as evidenced by the teachings of Brink et al., Genetics 1973, 73:273-296, cited both in the application and in an Information Disclosure Statement. Similarly, the W22 line is well known in the art as being an anthocyanin-deficient line and was described as early as 1977 in Chen et al., Biochem Genet. 1977 April 15 (3-4):333-346). The A188 line is also well known in the art and is included in the Ishida et al. reference cited by the Examiner in the instant Office Action. In light of the amendments to the claims and the well known nature of the alleles and lines in the art, Applicants respectfully request withdrawal of the instant rejection.

Claim 12 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite in its recitation of the term "events." Without acquiescing in the propriety of the Examiner's position, and solely to expedite prosecution of the instant application, Applicants have amended Claim 12 to identify that the F2 plants are obtained by sowing the selected F1 progeny identified in the Claim. In light of this amendment, Applicants respectfully request withdrawal of the instant rejection.

**Rejection Under 35 U.S.C. § 112, first paragraph (Enablement)**

Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skill in the art which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Specifically, the Examiner relies on Bennetzen (Plant

Mol. Biol., 42:251-269, 2000), as teaching that transposable elements can be differentially active under varying conditions, in order to assert that “[i]t would have been highly unpredictable at the time the claimed invention was made that transposable elements derived from diverse sources, such as, bacteria, yeast, Drosophila, humans etc., can be used...” Based on this alleged unpredictability, the Examiner contends that undue experimentation would have been required to determine how to practice the instantly claimed method using of mobilizable sequences derived from the full scope of transposable elements. Applicants respectfully disagree.

As a preliminary matter, Applicants point out that while Bennetzen does teach that endogenous transposable elements are often differentially active, Bennetzen does not discuss the activity of mobilizable sequences introduced into a maize line via recombinant DNA technology. Applicants respectfully submit that the gene silencing cited by the examiner is well known to be highly location-dependent, as in X-chromosome inactivation. Accordingly, without any further evidence, it is not appropriate to infer that the differential activity described in Bennetzen would be applicable to the methods of the instant claims, as the claims rely on the use of transgenic sequences rather than the endogenous mobilization sequences discussed in the cited art.

Applicants also note that Claim 1 specifically recites that the claims are directed to methods that rely on “an endogenous active transposase...” Thus, the Examiner’s argument that the claims are sufficiently broad to include mobilizable elements responsive to non-active transposases ignores the clear language of the claims. In fact, the Examiner appears to be arguing that the specification fails to enable embodiments that clearly fall outside the scope of the claims.

Finally, Applicants argue that the claims, as currently amended, are fully enabled by the specification alone and are fully in compliance with the ruling of *Genetech v Novo Nordisk*,

USPQ2d 1001, 1005 (Fed Cir 1997) cited by the Examiner at page 8 of the Office Action. In particular, Applicants note that the Examiner has conceded that the specification provides more than sufficient detail to enable one of skill in the art to identify and use several specific transposases capable of interrupting expression of a gene. (See page 6 of the Office Action). The identical routine experimentation necessary to enable those transposases is all that would be necessary to confirm the activity of any other transposase, regardless of its ultimate origin. As stated in the M.P.E.P., “[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.”<sup>2</sup> Accordingly, such routine experimentation cannot be considered undue.

In light of the foregoing, Applicants contend that the claims, as currently amended, are fully enabled by the specification and thus withdrawal of the instant claims is respectfully requested.

Claims 10 and 11 stand separately rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner alleges that the claims employ novel biological material comprising transposon tagged lines. Accordingly, the Examiner contends that the biological material must be deposited as it appears that it is not readily available to the public and the specification has not disclosed a repeatable process to obtain it. Applicants respectfully disagree.

As pointed out above, the alleles and lines employed in Claims 10 and 11 are both well known in the art and readily accessible to the public. For example, the maize line Rn-j::Ac has

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<sup>2</sup> (M.P.E.P. § 2164 citing *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int’l Trade Comm’n 1983), *aff’d sub nom. Massachusetts Institute of Technology v. A. B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed Cir 1983)).

been described Dellaporta et al., 1988 263-282, Gustafson and Appels (eds) Plenum Press NY, cited in the specification. Furthermore, Applicants submit that introgression of the Rn-j::Ac allele in any line to obtain a homozygous line for that allele is a routine procedure, which is well known in the art. Given the public accessibility and routine methods necessary to obtain all of the alleles and lines employed in Claims 10 and 11, Applicants respectfully submit that the claims are fully enabled by the specification and no deposit is necessary. Accordingly, Applicants request withdrawal of the instant rejection.

**Rejections Under 35 U.S.C. § 112, first paragraph (Written Description)**

Claims 1-4 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular the Examiner alleges that the specification does not provide adequate written description for “the genus of transposable elements active in monocots and genus of monocots lacking an active transposase...” (Page 12 of the Office Action). Applicants respectfully disagree.

As pointed out above, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. Applicants respectfully submit that it is well within the ordinary skill of the art to identify an active transposable element, and the examiner has not provided any evidence to the contrary. Furthermore, the claims, when read as a whole, necessitates two parental lines, the first one lacking the active transposase and the second that will carry the transposase. Once the second line is chosen, the

person of skill in the art know which type of transposase is to be used and will need to be absent in the first line. Accordingly, it is a matter of routine experimentation to test the first line for the presence or absence of the transposase. Given that the claim must be read as a whole, and since the functional domain that is to be absent from the first line is the transposase of the second line, Applicants respectfully submit that the specification contains sufficient written description to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Accordingly, withdrawal of the instant rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. § 102(b)**

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by Perez et al., WO 98/38323. In particular, the Examiner alleges that the method for obtaining a transgenic monocotyledon plant containing a gene of interest that is free of ancillary sequence, contains each and every limitation of the rejected claims.

Applicants respectfully traverse the foregoing rejection and assert that the instant claims are not anticipated by Perez et al. A proper rejection of the claims requires the Examiner to show that each and every element as set forth in the claim is found, either expressly or inherently, in the asserted reference.<sup>3</sup> This has not been done.

Although Perez et al. does disclose a method for the introduction of a gene of interest and the removal of ancillary sequences, Perez et al. does not teach that the active transposase should or could be located within a phenotypic marker for excision as in the rejected claims. In fact, the transposase coding sequence described in Perez et al. is located near a GUS marker, but not

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<sup>3</sup> See, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

within that marker. Furthermore, it is indicated that Ac transposase used in Perez et al. does not contain its 5' end, which includes the Ds element essential element for auto-excision activity. Since each and every element of the rejected claims is not found in Perez et al, as required under 35 U.S.C. § 102(b), reconsideration and withdrawal of the instant rejection is requested.

Claims 1-3 and 6-8 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yoder et al., WO 98/38323. In particular, the Examiner alleges that the method for obtaining a transgenic monocotyledon plant containing a gene of interest that is free of ancillary sequence, contains each and every limitation of the rejected claims.

Applicants respectfully traverse the foregoing rejection and assert that the instant claims are not anticipated by Yoder et al. As pointed out above, a proper rejection of the claims requires the Examiner to show that each and every element as set forth in the claim is found, either expressly or inherently, in the asserted reference. This has not been done.

As was the case of Perez et al., Yoder et al. fail to teach the inclusion of an active transposase within a phenotypic marker for excision as required by the rejected claims. Since, as above, each and every element of the rejected claims is not found in Yoder et al, as required under 35 U.S.C. § 102(b), reconsideration and withdrawal of the instant rejection is requested.

#### **Rejections Under 35 U.S.C. § 103(a)**

Claims 9 and 13-14 stand rejected under 35 U.S.C. § 103(a), as unpatentable over Perez et al., in light of Ishida et al., Nature Biotech. 14(6):745-750, 1996). In particular, the Examiner argues that it would have been prima facie obvious to one skilled in the art at the time the invention was made to modify Perez et al.'s method for obtaining a transgenic corn plant



containing a gene of interest that is free from foreign ancillary sequence (as discussed above) by using inbred line A188 taught by Ishida et al. Applicants respectfully point out that the examiner has not met his burden of establishing a prima facie case of obviousness. The Examiner must establish that the cited art teach or suggest each and every limitation of the pending claims.<sup>4</sup> This has not been done.

As outlined above, Perez et al. fails to teach or even suggest the use inclusion of the transposase within a phenotypic marker for excision. Furthermore, Perez et al. fails to teach or even suggest a transposase having auto-excision activity due to the lack of the appropriate 5' sequence necessary for auto-excision. Applicants submit that Ishidia et al. fails to cure the deficiency of Perez et al., as it also fails to describe a system wherein a transposase is included within a phenotypic marker for excision. In light of the foregoing, Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness and therefore withdrawal of the instant rejection is respectfully requested.

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<sup>4</sup> In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art."; See also M.P.E.P § 2143.03

**Conclusion**

To expedite allowance of this application, the Examiner is invited to telephone the undersigned if the Examiner believes a telephone call would be helpful in advancing prosecution.

Applicants believe that no fee, other than one month extension fee, is due in connection with the filing of this Response. If any additional fee is due, or overpayment made, with regard to this Response, the Transmittal and Fee Transmittal (submitted in duplicate herewith) authorizes the Director to charge any such fee, and credit any overpayment, to Deposit Account No. 02-4377.

Respectfully submitted,



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